10/20/2022

B.T.I. Biotechnology Institute, SL.
Jose Rivero
Qualified Person
Leonardo Da Vinci 14, Parque Technologico de Alava
Minano, Alava 01510
SPAIN

Re: K213106
Trade/Device Name: BTI Interna Dental Implant System UnicCa® - Prosthetic Components
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: September 19, 2022
Received: September 21, 2022

Dear Jose Rivero:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Andrew Steen
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213106

Device Name
BTI Interna Dental Implant System UnicCa - Prosthetic Components

Indications for Use *(Describe)*
The BTI Interna Dental Implant System UnicCa® - Prosthetic Components are intended to function in the mandible or maxilla to support single and multiple-unit temporary or definitive restorations on the BTI Interna® Dental Implant System.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510 (K) SUMMARY – K213106

I. SUBMITTER

B.T.I. Biotechnology Institute, SL.
Parque Tecnológico de Álava
C/Leonardo Da Vinci 14
01510 Miñano (Alava)
Spain

Establishment registration number: 3004417597

Phone: (+34) 945 297 030
Fax: (+34) 945 297 031

Contact Person: Mr. José Ramón Rivero
Date Prepared: October 20, 2022

II. DEVICE

Trade/Proprietary Name: BTI Interna Dental Implant System UnicCa® -Prosthetic Components.
Common or Usual Name: Endosseous Dental Implant Abutment
Regulation number: 21 CFR 872.3630
Classification Name: Endosseous Dental Implant Abutments
Regulatory Class: II
Product Code: NHA

III. PREDICATE DEVICE

The primary predicate device is the *Multi-unit Abutments for CONELOG®* from BioHorizons Implant Systems, Inc, which was subject of K203252 (cleared March 16, 2021).

In addition, the following reference devices have been identified for respective abutments/ prosthetic components described within this premarket notification:

- K053355, *BTI Interna Dental Implant System*
- K070533, *BTI Endosseous Dental Implant Angled Abutments*
- *K211952, BTI Interna Narrow/Plus Dental Implant System UnicCa®*

IV. DEVICE DESCRIPTION

The purpose of this 510(k) is to obtain marketing clearance for expanding the catalogue of abutments and prosthetic components for the Universal/ Universal Plus and Wide platform of the BTI Interna® Dental Implant System. The premarket notification includes a set of different abutments and screws: UNIT transepithelial abutments, Aesthetic Interfaces, Square Aesthetic Abutments, Angled Titanium Abutments and MULTI-IM transepithelial abutment screws compatible with the cited previous platforms of the BTI Implant System Unicca® in its internal engaging/non-engaging connection version. The implant to abutment connection of all set of abutments range from 4.1mm to 5.5mm. All subject devices are provided sterile via Gamma Radiation. All abutment configurations are not to be used with compatible BTI Interna implant bodies placed at angle (no angular correction), with the exception of the subject Angled Titanium Abutments.

The subject device Transepithelial abutments are straight abutments designed for single (UNIT) and multiple (MULTI-IM) screw-retained restorations. These transepithelial abutments are provided in a range of gingival height from 1.0mm to 4.0mm. All designs have a prosthetic diameter of 5.5mm.

Aesthetic Interfaces are the compatible attachments used to support definitive restorations over transepithelial abutments. Two models are available: Square Aesthetic Interfaces used in single restorations and Aesthetic Interfaces for multiple restorations. Square Aesthetic Interfaces are characterized by an engaging connection to UNIT transepithelial abutments and by four anti rotation lobes placed in prosthetic parts. Aesthetic Interfaces has a conical design with a non-engaging connection to MULTI-IM transepithelial abutments. Prosthetic diameter of aesthetic interfaces can be 5.5mm or 6.5mm, and prosthetic height, 3.5mm or 4.2mm. Aesthetic Interfaces are attached to the transepithelial abutments with their specific retention screws, MULTI-IM transepithelial abutments screws.

The proposed device Square Aesthetic Abutments are straight abutments design for single and multiple restorations in screwed or cemented restorations via traditional casting techniques. The engaging /non-engaging implant abutment connection has a diameter of 4.1mm or 5.5mm, depending on the compatibility with the implant. Square Aesthetic abutments are available in a range of gingival heights from 0.5 to 3.5mm.

Angled Titanium Abutments are premanufactured abutments directly used into the implant in single and multiple cemented restorations. These devices compensate up to 15° misalignment of implants between implant axis and prosthesis axis. Angled Titanium abutments are available in two gingival heights (2 or 4mm) and are compatible with Wide Implant Platform.

All abutments and interfaces are made of unalloyed conforming to ASTM F67 and are coated with titanium nitride (TiN). MULTI-IM transepithelial screws are manufactured in titanium alloy in accordance with ASTM F136, and the surface of the screw thread is coated with tungsten carbide/carbon and chromium (WC/C).

V. INDICATIONS FOR USE

The BTI Interna Dental Implant System UnicCa® - Prosthetic Components are intended to function in the mandible or maxilla to support single and multiple-unit temporary or definitive restorations on the BTI Interna® Dental Implant System.

VI. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

BTI Interna Dental Implant System UnicCa®- Prosthetic Components is substantially equivalent in terms of indications for use to the primary predicate device K203252. Slight differences in the language of the subject device Indications for Use Statement (IFUS) and reference devices do not affect the intended use for supporting a prosthesis to restore the patient's mastication functions. Minor differences between the IFUS for the subject devices and the primary predicate device include specific device names and compatible implant lines. Minor differences between the subject device IFUS and that of reference devices are related to design features and compatible implant lines. Furthermore, those reference devices mentioned are identified to overcome operating principle, fundamental design, materials, surface coating applied on abutment surface and screw thread – TiN and WC/C, packaging and sterilization to the predicate device.

Table 1 provides a comparison of the indication for use, device features, and other information to demonstrate that the subject device, is substantially equivalent to the primary predicate device and reference devices.

The proposed Transepithelial abutments are substantially equivalent to the transepithelial abutments cleared under K211952. The subject device and reference device K211952 both include straight abutment designs with engaging/non-engaging features, The subject transepithelial abutments and those cleared under K211952 are also substantially equivalent in terms of manufacturing materials, surface coating applied on the transepithelial sleeve and screw, TiN and DLC coating, respectively, in prosthesis attachment (screw-retained), abutment to implant interface (internal connection), packaging (Thermoform tray with peel top lid) and sterilization (gamma irradiation).

The subject device Aesthetic Interfaces and MULTI-IM transepithelial abutment screws are substantially equivalent to the Aesthetic Interfaces and retention screws for Narrow platform cleared under K211952 in terms of design, materials (CP Ti Grade 4 and Ti-6Al-4V), surface coating (TiN and DLC coating) and manufacturing workflow.

Square Aesthetic Abutments design are substantially equivalent to titanium abutment design cleared under K211952 both include straight abutments. The subject device and those titanium abutments cleared under K211952 are also substantially equivalent in terms of manufacturing material (CP Ti Grade 4), in prosthesis attachment (cemented or screw-

retained) and abutment to implant interface (internal connection, enganging/non-enganging design). Both devices are also used in single or multiple restorations via casting techniques.

The subject device Angled Titanium Abutment are substantially equivalent to those Angled Titanium Abutments cleared under BTI K070533, same design and same angulation, and the clearance K211952 supports surface coating. . These Angled Titanium Abutments do not present a new worst-case for fatigue testing as compared to the prior clearances for the same system of implants and abutments, so no new fatigue testing was conducted.

The reference device K053355 is for support dimensional differences in the implant platform compatibility, Universal/Plus and/or Wide platform.

Regarding sterilization, the subject devices (aesthetic interfaces, retention screws, square aesthetic abutments and angled titanium abutments) are supplied sterile by gamma radiation in a thermoformed tray with peel-off top lid. This sterilization method and packaging configuration is identical to the transepithelial abutments cleared in K211952. The additional subject abutments which are now provided sterile do not present a new worst-case for sterilization validation.

VII. NON-CLINICAL TESTING

A series of non-clinical testing has been presented to demonstrate that the proposed device is substantially equivalent to the predicate devices. Tests performed are as follows:

- Sterilization Validation to a sterility assurance level (SAL) of 10^{-6} according to ISO 11137-1, ISO 11137-2, and ISO 17665-1.
- Endotoxin Testing according to ANSI/AAMI ST72 *Bacterial endotoxins- Test methods, routine monitoring, and alternatives to batch* and methods consistent with USP <85> *Bacterial Endotoxins Test* and the FDA guidance document *Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile*, issued on January 21, 2016.
- Packaging Validation according to ISO11607-1 and ISO 11607-2.
- Shelf-life according to ASTM F88 and F1929
- Biocompatibility testing in conformance with ISO 10993-1.
- Characterization of TiN and WC/C coating surfaces on BTI devices including thickness, roughness, SEM images, abrasion testing, adhesion testing by static tensile test according to ASTM F1147, adhesion testing by dynamic shear bonding strength per ASTM F1160.
- Non-clinical worst-case MRI review was performed to evaluate the Subject device components in the MRI environment using scientific rationale and published literature (e.g., Woods, Terry O. , Jana G. Delfino and Sunder Rajan, "*Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices.*" Journal Testing and Evaluation 49.2 (2019):783-795), based on

the entire system including all variations (all compatible implant bodies, abutments, and fixation screws) and material composition. Rationale addressed parameters per the FDA guidance "*Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment*", including magnetically induced displacement force and torque.

VIII. CLINICAL TESTING

Clinical testing is not required.

IX. CONCLUSIONS

BTI Interna Implant System UnicCa® - Prosthetic Components has same intended use, has similar technological characteristics, are made of identical or similar materials to those clearances identified as primary predicate and reference devices. The subject device and the references devices cover similar range of dimensions, similar packaging, and similar sterilization method. In conclusion the data of the current submission demonstrate that the subject device is substantially equivalent to the predicate and references devices.

Table 1: Comparison of *BTI Interna Dental Implant System UnicCa®- Prosthetic components* with selected predicate and reference devices.

	Subject Device	**Primary Predicate Device**	**Reference Device**	**Reference Device**	**Reference Device**	
	BTI Interna Dental Implant System UnicCa®- Prosthetic Components.	**K203252** **Multi-unit Abutments for CONELOG®**	**K053355** **BTI Interna Dental Implant System**	**K070533** **Endosseous dental implant angled abutments**	**K211952** **BTI Interna Narrow/Plus Dental Implant System UnicCa®**	**Substantial Equivalence Discussion**
Product Classification	Regulation No.: 21 CFR 872.3630 Product Code: NHA Device Class II	Regulation No.: 21 CFR 873.3630 Product Code: NHA. Device Class II	Regulation No.: 21 CFR 872.3640 Product Code: DZE Device Class II	Regulation No.: 21 CFR 872.3630 Product Code: NHA Device Class II	Regulation No.: 21 CFR 872.3640 Product Code: DZE Device Class II	Identical to primary predicate device
Indications for Use	The BTI Interna Dental Implant System UnicCa® - Prosthetic Components are intended to function in the mandible or maxilla to support single and multiple-unit temporary or definitive restorations on the BTI Interna® Dental Implant System.	The BioHorizons Multi-unit Abutments for CONELOG® are intended to function in the mandible or maxilla to support single and multiple-unit temporary or definitive restorations on CONELOG dental implants	Dental implant system comprising endosseous titanium implants and prosthetic elements to be attached to the implants, as well as auxiliary elements for surgical and prosthetic procedures. The intended use of the system is the restoration of missing teeth in partially or fully edentulous patients and/or the fixation of overdentures to restore or enhance the chewing capacity of patients.	Endosseous dental implant angled abutments are premanufactured prosthetic components directly connected to the Endosseous dental implant and are intended for use as aids in prosthetic rehabilitation. They can be used in singled and multi-unit restorations where angled correction is required.	The BTI Dental Implant System UnicCa® for oral implant surgery is to be used for the partial or total replacement of teeth in edentulate patients. Once attached to the bone, the implants act as an anchor for various fixed or removable prosthetic solutions that can be used to improve or restore a patient's mastication function. In the case of 5.5 – 6.5mm long UnicCa® implants should be used in a two-stage surgical procedure. These implants are indicated for delayed loading. These implants are indicated only for straight abutments and to support permanently fixed restorations. In the case of Tiny® 3.0 UnicCa® implants: These implants shall be used only to replace maxillary lateral incisors and	Equivalent to primary predicate device.

	Subject Device	**Primary Predicate Device**	**Reference Device**	**Reference Device**	**Reference Device**	**Substantial Equivalence Discussion**
	BTI Interna Dental Implant System UnicCa®- Prosthetic Components.	**K203252** **Multi-unit Abutments for CONELOG®**	**K053355** **BTI Interna Dental Implant System**	**K070533** **Endosseous dental implant angled abutments**	**K211952** **BTI Interna Narrow/Plus Dental Implant System UnicCa®**	
					mandibular lateral and central incisors. Immediate loading is recommended when there is good primary stability and an appropriate occlusal load.	
Reason for Predicate/ Reference Device	Not applicable	Indications for Use	Abutment/implant connection design and implant platform compatibility.	Angled Titanium abutments design, material, and usage.	Prosthetic components design, materials, surface coating and manufacturing workflow.	-
Designs	Transepithelial Abutments, Interfaces, Angled Titanium abutments, Aesthetic Abutments and Screws.	Multi-Unit Straight abutment, Multi-Unit Angled Abutment, Copings, prosthetic screws and temporary cap.	Healing abutments and caps, Temporary abutments, **Titanium** and Gold **Abutments**, **Transepithelial abutments**, **Cylinders**, and **Screws.**	**Angled Titanium abutments**	Healing abutments, Temporary abutments, **Titanium Abutments, Transepithelial abutments**, **Aesthetic Interfaces and Screws**	-
Restoration	Single & Multiple	Single unit & Multi-unit	Single & Multiple	Single & Multiple	Single & Multiple	Identical to reference devices.
Compatible Implant Platform (Diameter Ø=mm)	Interna Universal/ Plus Ø= 4.1 Wide Platform Ø = 5.5	Ø = 3.3- 4.3	Interna Universal/ Plus Ø = 4.1 Wide Platform Ø = 5.5	Interna Universal/Plus Ø =4.1 Externa Universal Ø =4.1 Externa Wide Ø = 5.5 Tiny Ø=3.7 Narrow Ø=4.2	Interna Narrow Ø = 3.5 Interna Universal Plus Ø = 4.1	Identical to reference device K053355
Implant to Abutment connection	Internal	Internal	Internal	Internal, External	Internal	Equivalent to primary predicate

		Subject Device	**Primary Predicate Device**	**Reference Device**	**Reference Device**	**Reference Device**	**Substantial Equivalence Discussion**
		BTI Interna Dental Implant System UnicCa®- Prosthetic Components.	**K203252** **Multi-unit Abutments for CONELOG®**	**K053355** **BTI Interna Dental Implant System**	**K070533** **Endosseous dental implant angled abutments**	**K211952** **BTI Interna Narrow/Plus Dental Implant System UnicCa®**	
							device and identical to reference devices.
		Engaging/ Non-engaging	Engaging	Engaging/ Non-engaging	Non-Engaging	Engaging/ Non Engaging	Identical to reference device K053355 and equivalent to reference device K211952.
Prosthetic Diameter (mm)		4.1 to 6.5	4.8	4.1 to 6.5 (Selected components design)	3.7 to 5.5 (Selected components design)	4.1 and 5.5 (Selected components design)	Identical to reference device K053355.
Abutment Angulation		0°, 15°	0°, 17°, 30°	0°	15°	0°	Identical to reference device K070533.
Gingival Height		Up to 4mm	2-4mm	Up to 4mm (Selected components design)	Up to 4mm (Selected components design)	Up to 4mm (Selected components design)	Identical to reference devices.
Material	**Abutments &Aesthetic Interfaces**	CP Titanium Grade 4	Titanium Alloy ASTM F136	CP Titanium Grade 4	CP Titanium Grade 4	CP Titanium Grade 4	Identical to reference devices. Same manufacturing material.
	Screws	Titanium Alloy Ti-6Al-4V	Titanium Alloy ASTM F136	Titanium CP Grade 4	-	Titanium Alloy Ti-6Al-4V	Identical to reference device K211952. Same manufacturing material.
Surface Coating	**Abutments &Aesthetic Interfaces**	Titanium Nitride	N.A	-	-	Titanium Nitride	Identical to reference device K211952.
	Screws	DLC Coating	N.A	-	-	DLC Coating (Tungsten Carbide/ Carbon and Chromium)	Same surface coatings.

	Subject Device	Primary Predicate Device	Reference Device	Reference Device	Reference Device	Substantial Equivalence Discussion
	BTI Interna Dental Implant System UnicCa®- Prosthetic Components.	**K203252** **Multi-unit Abutments for CONELOG®**	**K053355** **BTI Interna Dental Implant System**	**K070533** **Endosseous dental implant angled abutments**	**K211952** **BTI Interna Narrow/Plus Dental Implant System UnicCa®**	
	(Tungsten Carbide/ Carbon and Chromium)					
Sterilization	Sterile by gamma radiation	Sterile by irradiation	**Titanium abutments and Screws:** Non- sterile. To be sterilized by end user-moist heat.	**Angled Titanium Abutments:** Non-sterile. To be sterilized by end user-moist heat	**Transepithelial abutments:** Sterile by gamma radiation **Titanium Abutments, Aesthetic Interfaces and screws:** non-sterile. To be sterilized by end user-moist heat.	Equivalent to reference device K211952. Subject devices are all provided by sterile radiation and same packaging to those transepithelial abutments cleared under K211952.
Packaging	Thermoform tray with peel top lid.	Unknown	**Titanium abutments and Screws:** Thermosealed bag	**Angled Titanium Abutments:** Thermosealed bag.	**Transepithelial abutments:** Thermoform tray with peel top lid. **Titanium Abutments, Aesthetic Interfaces and screws:** Thermosealed bag	